REMARKS

In the Office Action, the Examiner rejected claims 1-40. By the present Response, Applicants have amended claims 1 and 14. These amendments do not add any new matter. Upon entry of these amendments, claims 1-40 will be pending in the present application and are believed to be in condition for allowance. In view of the foregoing amendments and the following remarks, Applicants respectfully request reconsideration and allowance of all pending claims.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

In the Office Action, claims 1-16 were rejected under 35 U.S.C. § 112, second paragraph. Applicants have amended independent claims 1 and 14, as discussed below, in order to address the Examiner's concerns and to place the present application in better condition for either appeal or allowance.

Applicants note that these rejections were *not* made in the first non-final Office Action. *See generally*, Office Action mailed June 21, 2007. Applicants respectfully submit that while these rejections are without merit, as discussed further below, the late nature of these particular rejections only serves to frustrate and unnecessarily protract the prosecution of the present application. Accordingly, Applicants respectfully remind the Examiner of his duties and obligations under 37 C.F.R. § 1.104 and MPEP § 707.07 to provide actions which are *complete as to all matters*. Therefore, despite the finality of the instant Office Action, Applicants respectfully submit that it *would be unfair for the Examiner to refuse entry of the present amendments* with regard to independent claims 1 and 14.

Independent Claims 1 and 14

In the instant Section 112 rejection of independent claim 1, the Examiner specifically stated that:

> As per claim 1, Examiner cannot determine if "using" (line 2) refers to "a method" or "a clinical research entity".

> For purposes of applying prior art, Examiner interprets this limitation to recite a method capable of providing a server system to a clinical research entity.
>
> Claim 1 further recites "a server system coupled to a centralized database and at least one client system" (line 2-3). Examiner is unable to ascertain if Applicant[s] intend [sic] to recite structural limitations within the scope of a method claim, or if Applicant[s] intend [sic] to recite structural and functional limitations to the extent necessary to give meaning to the method steps.
>
> For purposes of applying prior art, Examiner interprets this limitation to recite a method capable of providing a server coupled to a centralized database and at least one client system.

Id. at page 2. As amended, the preamble of independent claim 1 recites: "A method for managing clinical study (CS) information for a clinical research entity *via* a server system coupled to a centralized database and at least one client system, said method comprising..." (Emphasis added). Accordingly, Applicants submit that the present amendment to the preamble of independent claim 1 sufficiently clarifies that the use of a "server system coupled to a centralized database..." is meant to refer to the method and *not* the clinical research entity.

The Examiner also stated in the instant rejection that:

> Claim 1 further recites "tracking" (line 11). Examiner cannot ascertain the meaning of this limitation when read in light of the specification.
>
> For purposes of applying prior art, Examiner interprets this limitation to recite updating data.

Id. at page 3.

It is well established case law that during patent examination, the pending claims must be given an interpretation that is *reasonable* and *consistent* with the specification. *See In re Prater*, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969); *In re Morris*, 44 U.S.P.Q.2d 1023,

1027-28 (Fed. Cir. 1997); see also M.P.E.P. § 2111 (describing the standards for claim interpretation during prosecution). Accordingly, Applicants respectfully disagree with the Examiner's interpretation of the term "tracking" as being equated with the term "updating." Applicants note that the "tracking" of CS information, as recited by independent claim 1 is clearly defined and supported by paragraph 28 of the specification. This paragraph discloses that embodiments of the present invention may include a tracking component 66 which *tracks and cross-references data*. *See* Application, paragraph 28. Applicants submit that in managing a database, such as the recited "centralized database" of independent claim 1, that it may be necessary to track and cross-reference changes in the data in order to provide a user with the most current data or information. Thus, while the tracking component 66 *may* also be capable of modifying (e.g., updating) existing data in the database, the data to be updated is *first* identified by "tracking" and cross-referencing the data with newly acquired data via the tracking component 66. Accordingly, Applicants submit that while *tracking* the data may be a prerequisite to *updating* the data, the two steps are still distinct, and thus not identical, as alleged by the Examiner.

Moreover, Applicants note that this point is further evidenced by the plain language of the claim in question. For example, independent claim 1 *clearly* recites "tracking" CS information and "updating" the centralized database as being *two* separate steps of the recited method. Applicants remind the Examiner that, during prosecution, claim recitations must be interpreted as one of ordinary skill in the art would reasonably interpret the claim in view of the specification. *See In re American Academy of Science Tech Center,* 70 U.S.P.Q.2d 1827 (Fed. Cir. 2004). Thus, in view of the foregoing discussion, Applicants submit that given the plain language of the pending claims, one of ordinary skill in the art would *not* interpret "tracking," as recited by independent claim 1, to be analogous to "updating."

The Examiner further stated in the instant rejection that:

> Claim 1 further recites "information" (line 14). Based upon the broadest and most reasonable interpretation adopted by the Examiner, this step (line 14) recites that any information may be provided. As such, claim 1 is rejected because the provided information lacks a nexus with the remainder of the claim.

> For purposes of applying prior art, Examiner interprets this limitation to recite CS information.

Office Action, page 3. By this response, Applicants have amended line 14 of claim 1 to recite "providing CS information." In view of this amendment, Applicants respectfully submit that the Examiner's requested clarification of the recited claim term is addressed and, therefore, the Examiner's rejection with regard to this claim recitation is moot.

Further, with regard to independent claim 14, the Examiner stated that "[a]s per claims 14-16, these claims are rejected for at least the same rationale as applied to claims 1-13 above, and incorporated herein." *Id.* Accordingly, independent claim 14 has been similarly amended, as discussed above with regard to independent claim 1. Applicants submit that these amendments sufficiently address the Examiner's Section 112, second paragraph rejections with regard to independent claim 14.

In view the foregoing remarks, Applicants submit that amended independent claims 1 and 14 sufficiently address the Section 112, second paragraph rejections set forth by the Examiner in the instant Office Action and also provide the requisite clarification requested by the Examiner. *See id.* Accordingly, rejected dependent claims 2-13, which depend from independent claim 1, and rejected dependent claims 15-16, which depend from independent claim 14, are believed to be allowable by virtue of dependency from their respective parent claims. Therefore, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, of claims 1-16.

Claim Rejections Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1-9, 13-25, 29-38 under 35 U.S.C. § 102(b) as being anticipated by Brown, U.S. Patent No. 6,196,970 (hereinafter referred to as "Brown").[1] Applicants respectfully traverse this rejection.

[1] Applicants note that while the Examiner listed claims 1-3, 6-9, 13-14, 16-19, 22-25, 29-30, 32-33, and 36-38 in the Section 102 portion of the rejection, the Examiner also stated in the Section 103 rejection that claims 4-5, 15, 20-21, 31, and 34-35 were *also* rejected under Section 102(b) as anticipated by Brown, or alternatively, under Section 103(a) as obvious over Brown in view of Goldwasser. *See* Office Action, page 15.

Legal Precedent

Anticipation under Section 102 can be found only if a single reference shows exactly what is claimed. *See Titanium Metals Corp. v. Banner*, 227 U.S.P.Q. 773 (Fed. Cir.1985). For a prior art reference to anticipate under Section 102, every element of the claimed invention must be identically shown in a single reference. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir.1990). That is, the prior art reference must show the *identical invention "in as complete detail as contained in the ... claim*" to support a *prima facie* case of anticipation. *Richardson v. Suzuki Motor Co*., 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989) (emphasis added). Thus, for anticipation, the cited reference must not only disclose all of the recited features but must also disclose the *part-to-part relationships* between these features. *See Lindermann Maschinenfabrik GMBH v. American Hoist & Derrick*, 221 U.S.P.Q. 481, 486 (Fed. Cir.1984). Accordingly, Applicants need only point to a single element or claimed relationship not found in the cited reference to demonstrate that the cited reference fails to anticipate the claimed subject matter.

Moreover, during patent examination, the pending claims must be given an interpretation that is *reasonable* and *consistent* with the specification. *See In re Prater*, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969); *In re Morris*, 44 U.S.P.Q.2d 1023, 1027-28 (Fed. Cir. 1997); see also M.P.E.P. §2111 (describing the standards for claim interpretation during prosecution). Indeed, the *specification* is "the primary basis for construing the claims." *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). (Emphasis added). It is usually dispositive. *See id.* Interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *See In re Cortright*, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999); *see also* M.P.E.P. §2111. That is, recitations of a claim must be read as they would be interpreted by those of ordinary skill in the art. *See Rexnord Corp. v. Laliram Corp*., 60 U.S.P.Q.2d 1851, 1854 (Fed. Cir. 2001); *see also* M.P.E.P. § 2111.01. In summary, an Examiner, during prosecution, must interpret a claim recitation as one of ordinary skill in the art would reasonably interpret the claim in view of the specification. *See In re American Academy of Science Tech Center,* 70 U.S.P.Q.2d 1827 (Fed. Cir. 2004). With the foregoing legal precedent in mind, Applicants address the Section 102 rejection below.

The Examiner has improperly correlated the recited "user selected template" to a "protocol."

Applicants note that each of the independent claims pending in the present application recites "a plurality of templates." With regard to embodiments of the present invention, a template may be selected by a user from the "plurality of templates" and used to collect clinical study (CS) information. Further, each of the plurality of templates may contain data fields by which a patient may enter data, such as data related to a patient's name, sex, medical history, weight, height, age, etc. *See* Application, paragraph 15. A graphical representation of the recited "template" is illustrated in Fig. 3 of the present application. *See id.* Fig. 3. The recited plurality of templates provides a *standardized* format for storing and maintaining CS information in a digital medium. *See id.* at paragraph 4. Historically, such information and data has been maintained in paper form, wherein managing the information so that it may be viewed in a standardized format is difficult, time consuming, and costly. *See id.* at paragraphs 2-3. Accordingly, the use of a standardized "plurality of templates" provided by the embodiments of the present invention is directed towards overcoming the drawbacks of the prior art methods and systems for managing CS information. *See id.*

In the instant rejections of independent claims 1, 14, 17, 30, and 33, the Examiner has maintained the assertion that the recited "plurality of templates" is analogous to "a protocol," as disclosed by Brown. *See* Office Action, page 23. In particular, the Examiner stated that "information concerning the type of data to be collected and the protocol collectively are considered to be 'a template.'" *Id.* Applicants respectfully disagree with the Examiner's erroneous interpretation. As noted in a previously filed Response, the terms "template" and "protocol" are simply *not* comparable. *See* Response to Office Action mailed June 21, 2007, page 20. Applicants note that the term "protocol," when used in the context of clinical studies, as disclosed by both Brown and the present application, generally refers to "[a] plan for carrying out a scientific study or a patient's treatment regimen." *See* Definition 6 of "protocol." *Random House Dictionary of the English Language, Unabridged*, 2nd ed. (1987).

With this in mind, Applicants note that the background section of Brown addresses problems in the conventional use of protocols in clinical studies, such as a Food and Drug Administration ("FDA") drug clinical trial. Typically, in an FDA drug trial, the sponsor of an

experimental drug first submits an application and a testing protocol to the FDA. *See* Brown, col. 1, lines 44-46. In an initial phase of testing, such as Phase I of an FDA clinical trial, the testing protocol may include guidelines relating to the number of volunteers, and what factors are to be studied (e.g., drug dosage effects and drug metabolism characteristics). *See id.* col. 1, lines 48-52. In Phase II, the protocol may further include studying the effectiveness of the drug, adverse reactions, etc. *See id.* col. 1, lines 58-61. In accordance with the testing protocol, Phase II of the study may include further expanding the number of test subjects. *See id.* col. 1, lines 61-65. Indeed, the use of the term "protocol," by Brown appears to refer to the particular plan for carrying out an FDA drug study. Applicants submit that this appears to be in accordance with the general well-known definition of the term "protocol," as discussed above.

Brown notes several drawbacks, however, of the conventional methods for carrying out FDA drug testing. Generally, once the initial protocol is submitted, it is difficult to modify the protocol during the course of the study. For example, Brown discloses that one problem with the use of conventional protocols is the inability to evaluate and standardize self-assessments from participating patients. *See id.* col. 2, lines 32-44. Because it is both costly and impractical to keep a sufficient staff of medical experts on hand to interview or solicit feedback from each and every test subject, the study may rely heavily on self-assessments reported by the test subjects, which may often include "fuzzy" answers as to physical state and/or mood that are difficult to analyze objectively. *See id.* A further problem noted by Brown is the inability to modify a testing protocol in real time. *See id.* col. 2, lines 45-67. Though it may be desirable to alter an existing testing protocol based on data analyzed during a clinical study, often times, the clinical study data may not aggregated or entered until near the conclusion of the trial, thus making it impossible for a researcher or medical professional to effectively modify the protocol while the study is in process. *See id.*

To address the aforementioned drawbacks, Brown discloses a system and method designed to more effectively allow modification of testing protocols based on received data. In particular, Brown discloses that each participating subject is provided a "client device" on which the research protocol is installed. *See id.* col. 4, lines 1-6. Based on the particular protocol on the client device, a test subject may respond to questions, such as whether

symptoms were relieved after ingesting the drug, as well as other general questions directed towards the test subject's physical and mental well-being. *See id.* col. 4, lines 6-9. Depending on the nature of the drug being tested, the client device, operating under the testing protocol, may also instruct the test subject to enter data, such as from a glucose monitor (e.g., the drug may be designed to relieve diabetic symptoms), which although not explicitly disclosed by Brown, is presumably provided to the test subject along with the client device. *See id.* col. 4, lines 9-12. Still further, Brown discloses that as part of the patient self-assessment, the protocol may present narrowly structured questions as well as suggested answers, and that in the event of ambiguous or incomprehensible answers, the testing protocol may include formulating additional questions in order to more effectively direct the patient's response towards a more objectively analyzable answer. *See id.* col. 4, lines 12-19. Additionally, the testing protocol may also include providing a restricted set of possible answers (e.g., multiple choice, true/false). *See id.* These features are designed reduce or eliminate "fuzzy" answers.

Brown further discloses that the self-assessment response provided by the patient through the client device is relayed to a server by a communication uplink, such that the data may be received and aggregated with data received from other test subjects in real time and statistically analyzed by parameters, which may be set by the testing protocol. *See id.* As such, medical and research personnel monitoring the drug study may be able to modify the protocol in response to the received data. *See id.* col. 4, lines 29-31. Brown discloses that modifying the protocol may include using parameters identified in the received data to better identify subjects responding positively to treatment, identifying subgroups among the testing population, or initiating additional self-assessment inquiries based on the analyzed data. *See id.* col. 4, lines 31-39. In other words, Brown is directed towards a system and method for *modifying a protocol*, which appears to be defined as a plan for carrying out an FDA experimental drug study. Further, Brown also explicitly states that the protocol installed on the client device is an "intelligent message, [which] acts in place of a researcher, investigator, clinician or other medical expert." *Id.* col. 4, lines 65-67. (Emphasis added). Thus, it would appear that Brown intended for the protocol installed on the client devices to act as a thorough but automated form of soliciting feedback from each test subject, distributing guidelines or instructional messages for operating medical research equipment, such as the

above discussed glucose monitor, or the like, thereby reducing the need for constant supervision by medical experts. This is in accordance with solving the above discussed issues regarding the cost and impracticality of keeping a full staff of medical experts on hand to interview or solicit feedback day after day from what may be hundreds or even thousands of test subjects.

In contrast, the term "template," as recited by the independent claims, is focused on a device or interface containing "fields that prompt a user to enter specific CS (clinical study) data 92 or to display specific CS data 92." Application, paragraph 35. The use of a "template" allows the placing of the CS data in a *standardized format*, which facilitates viewing and analysis by medical experts. *See id.* at paragraph 4. For example, such fields may include a patient's name, sex, medical history, weight, height, age, etc. *See id.* at paragraph 15; Fig. 3. Indeed, in the present context, a template clearly includes a set of fields used to gather information. It is not, as the Examiner has alleged, analogous to a protocol.

In response to Applicants' arguments in the previously filed Response, the Examiner provided a dictionary definition of the term "template" as follows:

> Webster's II Dictionary, Second Edition defines "template" as "a gauge or pattern… used in making or copying something accurately."

Office Action, page 22. Moreover, to the extent that the Examiner relied on this dictionary definition, the Examiner further stated that:

> …it is noted that the features upon which [A]pplicant[s] rel[y] (i.e., a set of fields allowing "a user to enter specific CS (clinical study) data 92 or to display specific CS data 92 for a user to view and analyze") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specifications are not read into the claims.
>
> Assuming *arguendo* this limitation flows inherently therefrom, Brown teaches displaying a portion of the protocol to the research subject to extract a response via an input (Figure

> 2a level 206-207). Brown further teaches that a protocol can include questions for the subject (Abstract).

Id. at pages 23-24. Thus, it appears that the Examiner has flatly refused to consider Applicants' previously submitted arguments on the grounds that the *dictionary* definition of "templates" does not explicitly disclose "a set of fields."

While Applicants certainly appreciate the difficulty faced by the Examiner in interpreting the claims in view of the specification without improperly importing limitations from the specification into the claims, Applicants respectfully note that the Federal Circuit, sitting *en banc*, recently provided a summary and additional guidance regarding the proper interpretation of claims in view of the specification. *See Phillips v. AWH Corp.*, 75 U.S.P.Q.2d 1321 (Fed. Cir. 2005) (*en banc*). In *Phillips*, the Federal Circuit again emphasized the primacy of the specification in claim interpretation. Particularly, the *Phillips* court noted that the specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; *it is the single best guide to the meaning of a disputed term*." *Phillips*, 75 U.S.P.Q.2d at 1327 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)) (Emphasis added). Moreover, the court also noted that:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language *and most naturally aligns with the patent's description of the invention* will be, in the end, the correct construction.

Phillips, 75 U.S.P.Q.2d at 1328-29 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)) (Emphasis added). In other words, the case law clearly states that it is the ***specification*** itself is the *best* resource for interpreting a claim term.

With the foregoing legal tenet in mind, Applicants submit that the Examiner's reliance on a dictionary reference and refusal to consider the specification of the present application in interpreting the claims is not only in direct contrast with legal precedent established by both the former C.C.P.A. and the Federal Circuit, but also inconsistent with

the reading one skilled in the art would reach when interpreting the claims. As discussed above, the recited "template" is *clearly* defined and directed towards a standardized format having a set of fields for entering CS data. Application, paragraph 35. Further, the mere fact that the protocol of Brown might include submitting questions to a patient as part of a drug study would clearly not merit an interpretation by one of ordinary skill in the art that a "protocol" is analogous to the recited "template."

Moreover, Applicants note that to the extent that the recited "templates" of the pending claims have any relation whatsoever to "protocols," it is, as stated in the present application, that the CS information entered into the *user template* may be used to gather *protocols*. However, the user templates themselves are clearly not analogous to the protocols which they may be used to gather. *See id.*, paragraph 8. In contrast, Brown does not teach or suggest that a *protocol* is developed as a result of clinical information entered through a *template* or that a "protocol" allows user entry of CS data via a set of fields or the display of such data. Further, as discussed above, the recited templates are directed towards providing a *standardized* format for receiving, storing, viewing, and analyzing CS data. In other words, to streamline the management of CS data, a *standard* form is used to collect the data. This ensures uniformity amongst all the data collected in a particular study by using the *same* template throughout the course of a study. In contrast, Applicants submit that there is nothing *standardized* about the system and method disclosed in Brown. As discussed above, Brown is directed towards *continuously modifying* a testing protocol based upon the analysis of clinical study data. Thus, the protocol is *changing* throughout the course of the study. As such, Applicants submit that when considering these two terms in view of their respective specifications, it would be preposterous to suggest that a protocol is analogous to a standardized template. As such, Applicants assert that Brown does *not* teach or suggest a template, much less a *plurality of templates*, as recited by pending independent claims.

Brown fails to teach or suggest a "user selected template" selected from "a plurality of user-selected templates stored in a centralized database."

Applicants note that each of the independent claims pending in the present application generally recites the selection of a template (e.g., user selected template) from a plurality of templates stored in a centralized database. In particular, independent claim 1 recites a

method for managing clinical study (CS) data "...wherein *the user selected template* is selected from a *plurality of templates*." (Emphasis added). Independent claim 14 recites "using a template selected by a user from *a plurality of templates*." (Emphasis added). Independent claim 17 recites a system for receiving CS information "entered through a user selected template ... wherein the *user selected template* is selected from a *plurality of templates* stored in the centralized database." (Emphasis added). Independent claim 30 recites a server system configured to "use a template selected by a user from *the plurality of templates*..." (Emphasis added). Independent claim 33 similarly recites a computer program comprising code that "receives CS information ... through a user selected templates, wherein the user selected template is selected from a *plurality of templates*..." (Emphasis added).

Applicants submit that Brown fails to disclose this feature. As discussed above, the Examiner's assertion that a "protocol," as disclosed by Brown, is analogous to the recited "template," is erroneous and, therefore, Brown cannot possibly disclose *selecting a template* from a *plurality of templates*, as recited by the presently pending independent claims. However, even assuming, *arguendo*, that a "protocol" *could* somehow be correlated to the "template," Applicants submit that the Examiner's argument is still unfounded and without support.

As noted in a previously filed Response, even assuming a protocol could be properly correlated to a "template," Brown fails to disclose that the protocol is selected from a *plurality of protocols* (templates). *See* Response to Office Action mailed June 21, 2007, pages 19-20. As discussed above, an initial testing protocol is generally formulated and submitted to the FDA prior to receiving approval for testing a new drug. *See* Brown, col. 1, lines 44-46. The protocol is a plan or set of rules and guidelines for carrying out a scientific study and, in the context of clinical drug studies, may relate to guidelines for determining the number of volunteers, what factors are to be studied (e.g., drug dosage effects and drug metabolism characteristics), guidelines for studying the effectiveness of the drug, monitoring of adverse reactions, etc. *See id.* col. 1, lines 48-61. The protocol may further include guidelines for expanding the number of test subjects during later phases of the study. *See id.* col. 1, lines 61-65.

To improve conventional protocol-based clinical testing methods, Brown discloses a system and method that expedites the collection and analysis of drug testing data from the test subjects. As such, research experts monitoring the study may be better equipped to identify certain data points or trends for the purposes of modifying the testing protocol to optimize the collection of reliable data in subsequent stages of the study. However, nothing in Brown suggests that the clinical researches are selecting a protocol from a *plurality* of protocols. In fact, as will be appreciated by those skilled in the art, it would be it would be detrimental if different testing protocols were used simultaneously within the same study, as the reliability of the acquired data may be compromised.

In responding to Applicants' previous arguments with regard to this claim feature, the Examiner stated that:

> Brown teaches that:
>
> (a) the server device records the information concerning the type of data to be collected and protocol in the database (Figure 2a label 204);
>
> (b) the server device records the *modified* protocol in the database (Figure 2b label 218);
>
> (c) steps (a)-(b) are repeated (Figure 2b label 221), thereby creating a plurality of protocols stored in the database (It is noted that nowhere does Brown teach deleting, or otherwise expunging or purging, protocol from the database);
>
> (d) the medical research expert either leave the protocol unchanged or modify the protocol as necessary (It is noted that a protocol is "selected" by the medical research expert for implementation) (column 7 line 3-5).
>
> According to the teachings of Brown, a medical research expert is presented with the choice to either modify the protocol or leave the protocol as-is. When steps (a)-(b) are repeated, the database stores therein a plurality of protocols as the results of the medical research expert modifying the protocol during each repetition of the loop.

> Examiner submits that when the medical research expert leaves a protocol as-is, the medical research expert is in effect "selecting" to implement the instant protocol over the plurality of protocols implemented in previous loops.

Office Action, pages 21-22. (Emphasis added). In other words, it appears that the Examiner is suggesting that because Brown does not *explicitly* disclose that modifying the protocol includes removing or expunging the *previous* "versions" of the protocol, these "out-dated" protocols must remain somewhere in the database, thus constituting a plurality of protocols. Applicants respectfully disagree with the Examiner's interpretation.

Although Applicants acknowledge that Brown does not *explicitly* disclose that "old versions" of the testing protocol are discarded from the server, Applicants submit that the Examiner's interpretation of Brown is in clear contradiction with the interpretation one or ordinary skill in the art would reach. First, Applicants submit that the plain meaning of the terms "modifying or "changing" a protocol imply that a researcher is making a change or modification to an *existing* protocol. Accordingly, Applicants further submit that one of ordinary skill in the art would not interpret "modifying a protocol" to mean that a researcher creates a copy of the original protocol (which is identical to the original protocol), implements the desired changes in the copy of the protocol (creating the modified protocol), and then saves or otherwise stores the "modified" protocol alongside the "original protocol" in a server.

In accordance with the system and method disclosed by Brown, it is desirable to update (e.g., modify) the protocol based on acquired data. Therefore, a researcher would *always* want to use the *most recent* version of the protocol in order to acquire the most reliable data. Accordingly, Applicants submit that Brown does not explicitly disclose expunging the old protocol versions because under the system and method of Brown, one of ordinary skill in the art could infer that these old and out-of-date protocols would *never* be used again. To provide a hypothetical example, suppose a researcher desires to conduct a study regarding a drug for reducing the occurrence of facial acne in young adults and submits an application and testing protocol to the FDA, in which the submitted protocol initially calls for an equal sample of male and female test subjects. Let us suppose that an analysis of the

research data from a first testing phase indicates that the drug is not effective in female test subjects, but appears to be highly effective in male test subjects. Accordingly, the research experts monitoring the study may find it pertinent to modify the existing testing protocol, for example, to exclude future data received from the already participating female subjects in order to prevent skewing of the test results demonstrating the effectiveness of the drug in male subjects and/or to exclude selection of additional female test subjects when selecting additional test subjects for subsequent FDA testing phases.

Keeping the above hypothetical in mind, Applicants submit that it would not be logical nor would it be efficient to keep the original protocol because upon realization that female test subjects should not be included in future testing, there would be never be a need to revert to the original protocol. Thus, contrary to the Examiner's assertion, Applicants submit that one or ordinary skill in the art would acknowledge that the passages of Brown which disclose "modifying" or "changing" a protocol are directed towards making changes in an *existing* protocol, *without* instantiating a *new* protocol each time a modification is performed. Thus, even assuming, *arguendo*, that the recited "templates" could be analogized with a "protocol," Applicants respectfully assert that Examiner's inferred assertion that Brown discloses selecting a protocol from a plurality of protocols is without support.

Brown fails to teach or suggest "each of the plurality of templates configured to correspond to specific clinical studies."

As discussed above, a drawback in prior art clinical study (CS) data management is the lack of a standardized format for maintaining CS data. *See* Application, paragraphs 2-3. Conventional CS data management methods may involve maintaining data in paper form. *See id.* For clinical research entities that conduct multiple clinical studies simultaneously, maintaining CS data in manner wherein it may be effectively utilized by a plurality of people can be both difficult and costly. *See id.*

The present application is directed towards providing a standardized format for acquiring and storing CS data, thereby facilitating the viewing and analysis of the data by medical personnel. *See id.* at paragraph 4. Specifically, the present claims are directed towards systems, methods, and computer programs which provide a plurality of standardized

templates, each of contains a plurality of fields for receiving CS data. *See id.* at paragraph 35. Moreover, each of the plurality of templates may be associated with a specific clinical study. *See id.* at paragraph 36. For example, a "generic template" may be used to create a specific template corresponding to a specific clinical study. *See id.* In other words, the present application discloses that in a given plurality of templates, each *respective* template may correspond to a specific *respective* clinical study. Accordingly, embodiments of the present invention are particularly useful in aiding clinical research entities, which may engage in numerous different clinical studies simultaneously, to better maintain CS data and, therefore, improve viewing, analysis, and management of the CS data.

With regard to the above discussed features, Applicants further note that each of the independent claims pending in the present application recites that each of a "plurality of templates" is configured to correspond to "specific clinical studies." Applicants submit that this recited feature is not disclosed by Brown. As discussed above, the Examiner's assertion that a "protocol," as disclosed by Brown, is analogous to the recited "template," is erroneous. Therefore, Brown cannot possibly disclose a *plurality of templates*, wherein *each of the plurality of templates corresponds to specific clinical studies*, as recited by the presently pending independent claims. However, even assuming, *arguendo*, that a "protocol" *could* somehow be correlated to the "template," and that Brown could be interpreted as disclosing a "plurality of protocols," Applicants submit that nothing in Brown suggests that each of the "plurality of protocols" correspond to specific clinical studies.

As discussed above, the Examiner asserted that Brown discloses a plurality of protocols based on the observation that Brown fails to *explicitly* disclose discarding "old versions" of protocols after the protocol is modified in response to the analysis of drug testing data. Assuming momentarily for the sake of argument that the Examiner is correct in his interpretation of the Brown reference and that Brown *does* indeed disclose a plurality of protocols, the plurality of protocols would comprise of different "versions" of the testing protocol, with newer versions of the protocol being created each time the protocol is modified. However, Applicants note that under the Examiner's interpretation, *each* of the plurality of protocols corresponds to the *same* clinical drug test. In other words, even though

the original protocol may have been modified to "produce" a new updated protocol (thus a plurality of protocols), both protocols would still correspond to the *same* clinical study.

Therefore, even under the assumption that the Examiner's assertion that Brown teaches a "plurality of protocols" is credible, Applicants submit that there is absolutely no teaching or suggesting that each of the plurality of protocols corresponds to different *specific clinical studies*. They would, in fact, correspond to the *same clinical study*.

Request Withdrawal of the Section 102 Rejections under Brown

As presented in the above paragraphs, Applicants have pointed out numerous deficiencies with regard to the Examiner's Section 102(b) rejections of independent claims 1, 14, 17, 30, and 33. Thus, in view of the foregoing discussion, Applicants submit that Examiner has not established a *prima facie* case of anticipation with regard to Brown. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) of independent claims 1, 14, 17, 30, and 33, as well as those claims depending therefrom.

Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 4-5, 15, 20-21, 31, and 34-35 under 35 U.S.C. § 103(a) as being unpatentable over Brown in view of Goldwasser, U.S. Patent No. 4,737,921 (hereinafter referred to as "Goldwasser"); rejected claims 10-11, 26-27, and 39-40 under 35 U.S.C. § 103(a) as being unpatentable over Brown in view of Rice et al., U.S. Pre-Grant Publication No. 2002/0042723 A1 (hereinafter referred to as "Rice"); and rejected claims 12 and 28 as being unpatentable over Brown in view of Applicants' Admitted Prior Art (hereinafter referred to as "AAPA"). Applicants respectfully traverse these rejections.

Legal Precedent

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish a *prima facie* case, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would

have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). In establishing a *prima facie* case for obviousness, "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 at 1729 (2007).

Dependent Claims Rejected Under the Combination of Brown, Goldwasser, and Rice

Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness with regard to dependent claims 4-5, 10-11, 15, 20-21, 26-27, 31, 34-35, and 39-40. As stated above, the Examiner rejected claim 4-5, 15, 20-21, 31, and 34-35 as obvious over Brown in view of Goldwasser and rejected claims 10-11, 26-27, and 39-40 as obvious over Brown in view of Rice. However, as discussed above, the Brown reference clearly does not disclose those claim features attributed to it by the Examiner. Specifically, Brown fails to disclose a "selecting a template plurality of templates" wherein "each of the plurality of templates corresponds to specific clinical studies." Moreover, the Examiner's use of Goldwasser and Rice does not obviate the deficiencies of Brown.

Accordingly, Applicants submit that the Examiner's Section 103 rejections of claims 4-5, 10-11, 15, 20-21, 26-27, 31, 34-35, and 39-40, which are based upon the Examiner's mistaken interpretation of the Brown reference, cannot establish a *prima facie* case of obviousness. As such, Applicants believe claims 4-5, 10-11, 15, 20-21, 26-27, 31, 34-35, and 39-40 are clearly allowable at least by virtue of their dependency from an allowable parent claim. Accordingly, Applicants respectfully request withdrawal of the Section 103 rejections under Brown and Goldwasser of claims 4-5, 15, 20-21, 31, and 34-35 and request withdrawal of the Section 103 rejections under Brown and Rice of claims 10-11, 26-27, and 39-40.

Improper Use of Official Notice with Regard to Dependent Claims 12 and 28

The Examiner rejected dependent claims 12 and 28 as being unpatentable over Brown in view of AAPA. In particular, the Examiner referred to his previous use of

Official Notice as "AAPA," stating that "Applicant[s] failed to properly traverse the Examiner's assertion" in the previous Office Action. Office Action, page 20. Applicants respectfully traverse both the instant rejection of claims 12 and 28, as well as the Examiner's repeated use of Official Notice.

First, Applicants direct to the Examiner's attention to pages 24-25 of the previously filed Response in which Applicants traversed the Examiner's previous use of Official Notice on the grounds that the combination of Brown and the facts inferred via Official Notice fail to establish a *prima facie* case of obviousness. *See* Response to Office Action mailed June 21, 2007, pages 24-25. Accordingly, Applicants submit that the Examiner's use of Official Notice was properly traversed in the previous Response. Therefore, the Examiner's classification of the facts taken under Official Notice in the previous Office Action as being "Applicants' Admitted Prior Art" in the instant Office Action is improper.

Moreover, with regard to the use of Official Notice in the instant Office Action, Applicants note that the Examiner has taken Official Notice with regard to the database actions of "(a) forming a query; (b) transmitting the query to the database; (c) parsing of the query by the database; (d) retrieving information stored in the database as indicated by the result of (c); [and] (e) returning the result of (d) for display; is old and well established in the art of database." Office Action, page 20. However, as discussed above, Brown does not disclose *selecting a template from plurality of templates stored in a centralized database, each of the plurality of templates corresponding to specific clinical studies*, as recited by independent claims 1 and 17, upon which claims 12 and 28 depend, respectively. Applicants further note that the Examiner's use of Official Notice does not obviate the deficiencies of Brown. As such, claims 12 and 28 are believed to be clearly patentable at least by virtue of their dependency from an allowable parent claim.

Further, Applicants again challenge the Examiner's use of Official Notice in the instant Office Action. Even if the general query steps of claims 12 and 28 could be inferred from unidentified art, the Examiner still bears the burden of establishing a *prima facie* case based upon a reasonable combination with Brown and some likelihood of

success. In this case, Brown does not disclose entering information into a database in the manner set forth in claims 1 or 17. As such, the query steps of claims 12 and 28 do not appear combinable with Brown. Thus, the mere citation of Official Notice fails to provide the requisite likelihood of success in this regard, and is therefore traversed.

Conclusion

In view of the remarks and amendments set forth above, Applicants respectfully request allowance of the pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date: January 26, 2008

/Patrick S. Yoder/

Patrick S. Yoder
Reg. No. 37,479
FLETCHER YODER
P.O. Box 692289
Houston, TX 77269-2289
(281) 970-4545